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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/873,645 | 06/04/2001 | Paul D. Taylor | P-633 | 4460 |
| 25732 | 7590 | 01/27/2006 | EXAMINER | |
| KEITH JOHNSON, ESQ. TRANSGENOMIC, INC. 12325 EMMETT STREET OMAHA, NE 68164 | | | CLOW, LORI A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1631 | |
| DATE MAILED: 01/27/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/873,645 | TAYLOR ET AL. | |
| | Examiner | Art Unit | |
| | Lori A. Clow, Ph.D. | 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 08 November 2005.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 13-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 13-16 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____.

DETAILED ACTION

Applicants' arguments, filed 8 November 2005, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 13-16 are currently pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 still recites "a system for computer implemented adjustment to generate values useful for grouping". This is an intended use of the system and it is unclear what limitation the grouping imparts to the system. Clarification is requested.

Claim 13 has been amended to recite "a computer having a processor and a memory, wherein the processor plots sets of data from a plurality of chromatographic elutions...wherein each set of data is obtained from the separation of a DNA mixture". These appear to be method step, therefore it is unclear what limitation of the **system** this step is intended to provide. As such, the claim is unclear. Clarification is requested. See note below.

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Claim 13 has been amended to recite “for comparison with values from control profiles to detect mutations in the sample DNA”. It is unclear what limitation of the system (product) is intended by this step. Clarification is requested.

Claim 15 recites “the system of claim 13 wherein said processor further comprises the steps of”. It is unclear what limitation to the system is intended by this recitation. Does Applicant intend that the processor comprise instructions for performing steps or some other limitation? Clarification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Note: For purposes of a prior art search, claim 13 and dependent claims are interpreted as a system comprising a processor wherein the processor is configured to perform the steps of plotting by time point selection etc. As such, the data that is generated by elution profiling is not interpreted to limit the claimed **system**, as it is non-functional descriptive material. See *In re Gulak* (Cf. *In re Gulack*,

703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability) (MPEP 2106).

Claims 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunt (Quantitative Pattern Recognition Using Nonlinear Model-Based Analysis. A Dissertation presented for PhD at The University of Tennessee, May 1998).

The instant claims are drawn to a system for adjustment of signal data and time data of chromatographic elution profiles, said system comprising a processor that plots elution data on a coordinate system with a first axis of time values and a second axis of response values. The system further selects time points defining a time span, adjusts a baseline by applying a slope

factor, normalizes peak height, and shifts profiles along a first axis such that all of the profiles intersect.

In regard to claim 13, Hunt teaches the analysis between observed time series patterns and physical phenomenon of interest in using pattern recognition and signal processing theory (page 5, lines 13-16). Specifically, Hunt teaches baseline estimation of chromatographic data applied to several chromatograms (page 107, section 8.2). Baseline estimations are made by a fitting function to determine a minimum and maximum signal.

Peak modeling is then performed (page 110, section 8.3), in which estimates of peak model parameters are made by analyzing time series information. Once peaks are located, the first peak amplitude above baseline is obtained. Further modeling is performed using least squares analysis to generate a peak center (page 113, section 8.3.2). The sliding window approach is used to fit multiple peaks across a time series using least squares minimization (page 147, line 18-20).

Hunt teaches a scale from 0 to 1, based upon magnitude of the peak, as in claim 14 (page 109, Figure 8.3).

Hunt does not specifically teach Matched Ion Polynucleotide Chromatography. However, it would have been *prima facie* obvious to one or ordinary skill in the art at the time of the invention to have used the system of Hunt to adjust signal and time data of MIPC profiles. One would have been motivated to do so because the system of Hunt plots chromatographic elution profiles and Hunt states that fundamental components to **any** peak detection and measurement operation involve the accurate estimate of a baseline (page 16, section 1.4.5) and peak adjustment (page 17, section 1.4.6).

No claims are allowed.

Conclusion

The outstanding rejection under 35 USC 112, 1st paragraph has been withdrawn on view of the amendments to the claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

January 23, 2006
Lori A. Clow, Ph.D.
Art Unit 1631
Lori A. Clow

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
1/23/06